MAY - 1 2003

Allegiance
a Cardinal Health company

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
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SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Airlife® Misty Max 10™ Nebulizer K023602

Submitter:	Allegiance Healthcare Corporation 1500 Waukegan Road MPWM McGaw Park, IL 60085
Regulatory Affairs Contact:	Sharon Nichols
Telephone:	(847) 785-3311
Date Summary Prepared:	April, 2003
Common Name:	Airlife ® Misty Max 10™ Nebulizer
Classification:	Class II per 21CFR § 868.5630
Predicate Device:	Airlife Misty Nebulizer
Description:	The nebulizer is a single patient use device which is filled with a fluid, typically respiratory medication, and connected to an air source via flexible tubing. The nebulizer works by having the fluid come into contact with the stream of gas. The gas shatters the liquid into small particles. These particles then impact a baffle that further reduces the size of the particles. The majority of the larger particles settle inside the nebulizer as a result of gravity and inertia, returning the mist to liquid to repeat the nebulization process. The smaller particles are then administered as the patient inhales. The treatment is completed when the majority of fluid is nebulized.

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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Airlife® Misty Max 10™ Nebulizer

Intended Use:	The Airlife Misty Nebulizer is a pneumatic nebulizer which nebulizes specific drugs for inhalation by a patient. The patient population includes infant, pediatric and adult patients. It's use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a small volume nebulizer. This product is a single patient use, non-sterile prescriptive device and is designed to be used in either a hospital or homecare environment.
Substantial Equivalence:	Airlife ® Misty Max 10™ Nebulizer is substantially equivalent to the Airlife® Misty-Neb Nebulizer in that: - the intended use is the same - the performance attributes are similar
Summary of testing:	All materials used in the fabrication of the Airlife® Misty Max 10™ Nebulizer were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". Comparative testing was performed using the proposed, predicate and Pari-LC with regards to particle size distribution testing. These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2003

Ms. Sharon Nichols
Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road, Building WM
McGaw Park, Illinois 60085

Re: K023602
Trade/Device Name: Airlife® Misty Max 10™ Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: March 31, 2003
Received: April 1, 2003

Dear Ms. Nichols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K023602

Device Name: Airlife®Misty Max 10™ Nebulizer

Indications For Use: The Airlife Misty Nebulizer is a pneumatic nebulizer which nebulizes specific drugs for inhalation by a patient. The patient population includes infant, pediatric and adult patients. It's use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a small volume nebulizer. This product is a single patient use, non-sterile prescriptive device and is designed to be used in either a hospital or homecare environment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023602